

115TH CONGRESS
1ST SESSION

S. 348

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate lower covered part D drug prices on behalf of Medicare beneficiaries.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 9, 2017

Mr. FRANKEN (for himself, Mr. REED, and Mr. BROWN) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate lower covered part D drug prices on behalf of Medicare beneficiaries.

1 *Be it enacted by the Senate and House of Representa-*

2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Prescription Drug and

5 Health Improvement Act of 2017”.

6 **SEC. 2. NEGOTIATING FAIR PRICES FOR MEDICARE PRE-**

7 **SCRIPTION DRUGS.**

8 (a) NEGOTIATING FAIR PRICES.—

1 (1) IN GENERAL.—Section 1860D–11 of the
2 Social Security Act (42 U.S.C. 1395w–111) is
3 amended by striking subsection (i) (relating to non-
4 interference) and by inserting the following:
5 “(i) NEGOTIATING FAIR PRICES WITH DRUG MANU-
6 FACTURERS.—

7 “(1) IN GENERAL.—Notwithstanding any other
8 provision of law, in furtherance of the goals of pro-
9 viding quality care and containing costs under this
10 part, the Secretary shall, with respect to applicable
11 covered part D drugs, and may, with respect to
12 other covered part D drugs, negotiate, using the ne-
13 gotiation technique that the Secretary determines
14 will maximize savings and value for a covered part
15 D drug and plan enrollees (in a manner that may
16 be similar to Federal entities and that may include,
17 but is not limited to, formularies, reference pricing,
18 discounts, rebates, and other price concessions), with
19 drug manufacturers the prices that may be charged
20 to PDP sponsors and MA organizations for such
21 drugs for part D eligible individuals who are enrolled
22 in a prescription drug plan or in an MA–PD plan.
23 In conducting such negotiations, the Secretary shall
24 consider the drug’s current price, initial launch
25 price, prevalence and usage, and approved indica-

1 tions, the number of similarly effective alternative
2 treatments for each approved use of the drug, the
3 budgetary impact of providing coverage under this
4 part for such drug for all individuals who would like-
5 ly benefit from the drug, and evidence on the drug's
6 effectiveness compared to similar drugs.

7 “(2) USE OF LOWER OF VA OR BIG FOUR PRICE
8 IF NEGOTIATIONS FAIL.—If, after attempting to ne-
9 gotiate for a price with respect to a covered part D
10 drug under paragraph (1) for a period of 1 year, the
11 Secretary is not successful in obtaining an appro-
12 priate price for the drug (as determined by the Sec-
13 retary), the Secretary shall establish the price that
14 may be charged to PDP sponsors and MA organiza-
15 tions for such drug for part D eligible individuals
16 who are enrolled in a prescription drug plan or in
17 an MA–PD plan at an amount equal to the lesser
18 of—

19 “(A) the price paid by the Secretary of
20 Veterans Affairs to procure the drug under the
21 laws administered by the Secretary of Veterans
22 Affairs; or

23 “(B) the price paid to procure the drug
24 under section 8126 of title 38, United States
25 Code.

1 “(3) APPLICABLE COVERED PART D DRUG DE-
2 FINED.—For purposes of this subsection, the term
3 ‘applicable covered part D drug’ means a covered
4 part D drug that the Secretary determines to be ap-
5 propriate for negotiation under paragraph (1) based
6 on one or more of the following factors as applied
7 to such drug:

8 “(A) Spending on a per beneficiary basis.

9 “(B) Spending under this title.

10 “(C) Unit price increases over the pre-
11 ceding years.

12 “(D) Initial launch price.

13 “(E) Availability of similarly effective al-
14 ternative treatments.

15 “(F) Status of the drug as a follow-on to
16 previously approved drugs.

17 “(G) Any other criteria determined by the
18 Secretary.

19 “(4) PDP SPONSORS AND MA ORGANIZATION
20 MAY NEGOTIATE LOWER PRICES.—Nothing in this
21 subsection shall be construed as preventing the spon-
22 sor of a prescription drug plan, or an organization
23 offering an MA–PD plan, from obtaining a discount
24 or reduction of the price for a covered part D drug

1 below the price negotiated under paragraph (1) or
2 the price established under paragraph (2).

3 “(5) NO AFFECT ON EXISTING APPEALS PROC-
4 ESS.—Nothing in this subsection shall be construed
5 to affect the appeals procedures under subsections
6 (g) and (h) of section 1860D–4.”.

7 (2) EFFECTIVE DATE.—The amendments made
8 by this subsection shall take effect on the date of the
9 enactment of this Act and shall first apply to nego-
10 tiations and prices for plan years beginning on Jan-
11 uary 1, 2019.

12 (b) REPORTS TO CONGRESS.—

13 (1) SECRETARY OF HHS.—

14 (A) IN GENERAL.—Not later than 3 years
15 after the date of the enactment of this Act, and
16 every 6 months thereafter, the Secretary of
17 Health and Human Services shall submit to
18 Congress a report on the following:

19 (i) The negotiations conducted by the
20 Secretary under section 1860D–11(i) of
21 the Social Security Act (42 U.S.C. 1395w–
22 111(i)), as amended by subsection (a), in-
23 cluding a description of how such negotia-
24 tions are achieving lower prices for covered
25 part D drugs (as defined in section

1 1860D–2(e) of the Social Security Act (42
2 U.S.C. 1395w–102(e))) for Medicare bene-
3 ficiaries.

4 (ii) Data on spending under part D of
5 the Medicare program on covered part D
6 drugs, including data on covered part D
7 drugs with—

8 (I) spending on a per beneficiary
9 basis that is above the median spend-
10 ing on other drugs in the same class
11 or above the median spending of other
12 drug classes; and

13 (II) high unit cost increases over
14 the past five years, especially where
15 such increases are greater than the
16 increases for covered part D drugs in
17 general.

18 (iii) A list of the covered part D drugs
19 with no therapeutic substitute and data on
20 spending under part D of the Medicare
21 program on such drugs.

22 (iv) Access to covered part D drugs.

23 (v) Appeals by enrollees with respect
24 to covered part D drugs not included on
25 plan formularies.

(B) PUBLIC AVAILABILITY OF REPORT.—

2 The Secretary of Health and Human Services
3 shall publish on the Internet website of the
4 Centers for Medicare & Medicaid Services a
5 copy of each report submitted under subpara-
6 graph (A).

7 (2) MEDPAC.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study on the negotiations conducted by the Secretary under section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)), as amended by subsection (a), including a description of how such negotiations are achieving lower prices for covered part D drugs (as defined in section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e))) for Medicare beneficiaries.

(B) REPORT.—Not later than January 1, 2022, the Comptroller General of the United States shall submit to Congress a report on the study conducted under subparagraph (A), together with recommendations for improving such negotiations.

1 (c) CMI TESTING OF NEGOTIATING DRUG AND BIO-
2 LOGICAL PRICES TO IMPROVE VALUE.—Section
3 1115A(b)(2) of the Social Security Act (42 U.S.C.
4 1315a(b)(2)) is amended—

5 (1) in subparagraph (A), by adding at the end
6 the following new sentence: “The models selected
7 under this subparagraph shall include at least 3 of
8 the models described in subparagraph (D), which
9 shall be implemented by not later than 18 months
10 after the date of the enactment of the Prescription
11 Drug and Health Improvement Act of 2017”; and
12 (2) by adding at the end the following new sub-
13 paragraph:

14 “(D) MODELS OF NEGOTIATING DRUG AND
15 BIOLOGICAL PRICES TO IMPROVE VALUE.—The
16 models described in this subparagraph are the
17 following models for negotiating drug and bio-
18 logical prices under the applicable titles (includ-
19 ing under both parts B and D of title XVIII)
20 in order to improve the value of payments for
21 such drugs and biologicals under such titles:

22 “(i) Discounting or eliminating pa-
23 tient cost-sharing on high-value drugs and
24 biologicals.

25 “(ii) Value-based formularies.

- 1 “(iii) Indications-based pricing.
- 2 “(iv) Reference pricing.
- 3 “(v) Risk-sharing agreements based
- 4 on outcomes.
- 5 “(vi) Pricing based on comparative ef-
- 6 fectiveness research.
- 7 “(vii) Episode-based payments for
- 8 chemotherapy and other conditions deter-
- 9 mined appropriate by the Secretary.”.

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